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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,899	08/21/2003	John L. Sommer	P-11139.00	1340
27581	7590	01/03/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 01/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,899

Applicant(s)

SOMMER ET AL.

Examiner

Alyssa M. Alter

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-13 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 8-13 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed October 11, 2005 have been fully considered but they are not persuasive. The Applicant states that Holleman et al. (US Patent Publication 20040260355) does not teach "a flange extending from an inner lumen of the adaptor and the adapter is rotated about an axis extending from the proximal end to the distal end of the adapter". However, Holleman et al. does disclose a flange in the inner lumen of the adaptor or in the alternative, Holleman et al. in view of Peers-Trevarton (US 4,469,104). Peers-Trevarton discloses that it is well known to employ mechanical engagement in conjunction with electrical engagement to ensure proper contact.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-6 and 8-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/635166 (US Patent Publication 20050033371 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because Application 10/635,166 discloses a connector sleeve, which the examiner considers to be the adaptor since the adaptor connects the lead to the IMD, just like the connector sleeve. The medical system also has a retention element adapted to mechanically engage the lead connector element within the lumen and facilitate electrical connection between the sleeve, or adaptor, and the lead. Therefore, the examiner considers the retention element to be a flange. Furthermore, the examiner considers the ring formed on the external surface to be a sealing ring.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-6 and 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Sommer et al. (US Patent Publication 20050033371). Sommer et al. discloses an

implantable medical lead connector sleeve. The connector sleeve, which the examiner considers to be the adaptor, has a retention element adapted to mechanically engage the lead connector element within the lumen and facilitate electrical connection between the sleeve, or adaptor, and the lead. Therefore, the examiner considers the retention element to be a flange. Furthermore, the examiner considers the ring formed on the external surface to be a sealing ring.

The applied reference has a common inventors and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3, 6, 8 and 12-13 are rejected under 35 U.S.C. 102(e) as anticipated by Holleman et al. (US Patent Publication 20040260355) for reasons previously made of record or, in the alternative, are rejected under 35 U.S.C. 103(a) as obvious over Holleman et al. (US Patent Publication 20040260355) in view of Peers-Trevarton (US 4,469,104).

The Applicant argues that Holleman et al. "a flange extending from an inner lumen of the adaptor and the adapter is rotated about an axis extending from the proximal end to the distal end of the adapter".

However, In regards to claim 1, the functional language and introductory statement of intended use of claim 1 has been carefully considered but is not considered to impart any further structural limitations over the prior art. Since Holleman et al. utilizes an adaptor as claimed by the Applicant, Holleman et al. is therefore capable of rotating the adaptor about an axis. In addition nothing prevents Holleman et al. from rotating the adaptor. Therefore, the adaptor as disclosed by Holleman et al. is capable of being rotated about an axis.

Also, Holleman et al. does disclose contacts coupled to lead connector elements on page 2, paragraph 16. "FIG. 2 is a sectional view of adaptor 16 wherein receptacle port 32 is shown to include low-voltage contacts 80 and 82 and high-voltage contacts 84 and 86 for providing electrical connection to lead connector elements 44, 46, 48, and 50 respectively (FIG. 1); contact 80 is coupled to connector pin 22 and via a

conductor 72 and each of contacts 82, 84, and 86 are electrically coupled to connector rings 24, 26, and 28, respectively via conductors 74, 76, and 78a. Conductors 72, 74, 76 and 78a, extending through body 30 to adaptor connector terminal 20, are electrically isolated from one another”(page 2, paragraph 16).

According to Merriam-Webster Online Dictionary, a flange is “a rib or rim for strength, guiding, or for attachment to another object. Since the adaptor lumen is attaching to the lead connector elements, there is inherently a flange.

Furthermore, Holleman et al. also discloses on page 1, paragraph 14, that the connectors 13 and 15 in the connection header 12 are dimensioned to receive and make electrical and mechanical connection with connector rings 26 and 28, respectively, of adaptor connector terminal 20, or with connector elements 48 and 50 of lead connector terminal 42

“Adaptor 16 includes a connector terminal 20 adapted to engage within connector port 14 of a connector header 12 of IMD 10, and, as illustrated in FIG. 1, connector terminal 20 includes three connector rings 24, 26 and 28 and a connector pin 22. Connector header 12 is shown attached to a hermetically sealed enclosure or can 11 that contains a battery and electronic circuitry and other components. Can 11 may further serve as a high voltage electrode in conjunction with lead electrodes 54, 52, 66. Port 14, configured to receive either first lead connector terminal 42 or adaptor connector terminal 20, includes high-voltage connectors 13 and 15 of any of the known types that are electrically connected to the electronic circuitry through feedthrough pins of feedthroughs (not shown) mounted to extend through can 11. Connectors 13 and 15

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are dimensioned in diameter and are spaced apart in port 14 to receive and make electrical and mechanical connection with connector rings 26 and 28, respectively, of adaptor connector terminal 20, or with connector elements 48 and 50 of lead connector terminal 42. Such electrical and mechanical connection is effected either through the tightening of setscrews (not shown) as disclosed in U.S. Pat. Nos. 4,142,532 and 4,182,345, for example, or an action of inwardly extending force beams (not shown) as disclosed in U.S. Pat. Nos. 5,070,605 and 5,766,042, for example. Additional connectors 17 and 19 included in port 14 make mechanical and electrical contact with connector pin 22 and connector ring 24 of adaptor connector terminal 20 or with connector elements 44 and 46 of lead connector terminal 42. According to one embodiment of the present invention, connector pin 22 and connector ring 24 are adapted for low-voltage coupling in port 14 while connector rings 26 and 28 are adapted for high-voltage coupling in port 14. According to alternate embodiments of the present invention any two of connector rings 24, 26, 28 and connector pin 22 may be eliminated and a remaining two be adapted for high-voltage coupling in port 14" (page 1, paragraph 14).

Since Holleman et al. discloses that the connector header 12 has a port 14, which is capable of engaging either the adaptor 20 or lead 42. The adaptor port 32 is also configured to receive lead 42. Therefore, since both the port 14 as the port 32 are both configured to receive lead 42, there is inherently the same mechanical and electrical contacts disposed within both ports. The examiner considers the mechanical

engagement to be facilitated by a flange as depicted in figure 1 and based on the previous recited definition of flange.

As to claims 8, Holleman et al. discloses on page 1, paragraph 14, that electrical and mechanical contact can be facilitated by "an action of inwardly extending force beams", which the examiner considers to be a resilient force beam.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

2. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being obvious over Holleman et al. (US patent Publication 20040260355), or the modified Holleman et al. as applied to claims 1-3, 6, 8 and 12-13 above, in view of Bischoff et al. (US 5,843,141). Holleman

et al. discloses the claimed invention except for the sealing rings. Bischoff et al. teaches that it is known to use sealing ring proximal and distal to the lead connectors as set forth in column 1, lines 54-63. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the leads as taught by Holleman et al. with the leads with sealing rings as taught by Bischoff et al., in order to prevent fluid entry.

3. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being obvious over Holleman et al. (US patent Publication 20040260355), or the modified Holleman et al. as applied to claims 1-3, 6, 8 and 12-13 above, in view of Peers-Trevarton (US 4,469,104). Holleman et al. discloses the claimed invention except for the corresponding protrusion or depressions to mate with the flange. Peers-Trevarton teaches that it is known to utilize protrusions and depressions to mechanically and electrically engage the lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical connections of the lead as taught by Holleman et al. with the electrical and mechanical connections as taught by Peers-Trevarton since such a modification would be a substitution of known functional equivalents by substituting electrical connectors to electrically engage the lead.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction

of the following is required: flange. The examiner recommends referring to the protruding key 82 in figure 5 as a flange.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

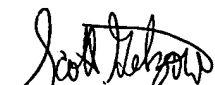
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Scott M. Gelzow
Primary Examiner


Alyssa M Alter
Examiner
Art Unit 3762